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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,462	05/05/2006	Makrina Savvidou	HO-P03236US0	8934

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EXAMINER	
SINGH, ANOOP KUMAR	
ART UNIT	**PAPER NUMBER**
1632	
MAIL DATE	**DELIVERY MODE**
08/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,462	SAVVIDOU ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,18,21,22,25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,18,21,22,25,27 and 28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments to the claims filed on October 17, 2005 have been received and entered. Claims 3-4,6-7, 9, 11, 18, 21-22 and 25 have been amended, while claims 12-17, 19-20, 23-24 and 26 have been cancelled. Applicants have also added claim 27-28.

Claims 1-11, 18, 21-22, 25 and 27-28 are under consideration.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11, drawn to a method of identifying whether or not a pregnant woman is at risk of developing pre-eclampsia comprising measuring asymmetric dimethylarginine (ADMA) in the pregnant woman and thereby determining whether or not the woman is at risk of developing pre-eclampsia or determining whether or not her fetus is at risk of developing IUGR.

Group II, claims 18, 22, drawn to a non-human pregnant female animal in which pre eclampsia has been established by administration of ADMA.

Group III, claim 21, drawn to a method for establishing pre eclampsia in an non-human pregnant female animal or establishing IUGR in her fetus comprising administering ADMA to the animal in amount sufficient to cause pre eclampsia or IUGR.

Group IV, claims 21 and 25, drawn to a method of identifying a substance which prevents or treat pre eclampsia or IUGR by administering candidate substance to an animal in which pre eclampsia has been established or to a DDAH deficient animal.

Group V, claims 21, 27 and 28, drawn to a method of inhibiting or preventing pre eclampsia in a pregnant women or preventing IUGR in her fetus by administering to the pregnant women an effective amount of an antagonist of ADMA activity.

The inventions listed as groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V is measuring the level of ADMA in the pregnant woman to determine if the subject is at risk of developing pre-eclampsia. Prior to instant invention, Ellis et al (Acta obstetricia et Gynecologica Scandinavica., 2001, vol. 80, no. 7, pages 602- 608) teach a method comprising measuring plasma concentration of ADMA in pregnant women at 24-32 weeks gestation to determine whether subject is at the risk of developing pre eclampsia or IUGR. Since the method steps disclosed by cited art are same as one disclosed in claim 1. Therefore, the instant technical feature does not contribute over prior art.

In addition, the inventions are distinct fro each from other because of the following reasons: Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and require different composition, which provide different mode of operation and require distinct, non-coextensive considerations. In the instant case method of diagnosing pre-eclampsia by determining the ADMA in a women is different and distinct as compare to a non human pregnant female animal that could be used as model for screening therapeutics against pre eclampsia or IUGR. The method steps for establishing pre eclampsia in a non human female animal is different from a method of identifying a substance that prevents or treat pre eclampsia by administering test agent to the nonhuman animal or a therapeutic method for treating or preventing pre eclampsia by administering an antagonist of ADMA activity. Each of these involves distinct and different method steps and composition and therefore, searching for distinct method steps and composition will not be coextensive and will require separate and independent searches in the patent and non-patent literature.

Each invention is directed to distinct goal, which comprises the use measuring level of ADMA for diagnosing pre eclampsia or IUGR in order to achieve its respective

and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
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